K123615

SECTION 5. 510(k) SUMMARY For IRIS

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

FEB 22 2013

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: November 20, 2012

2. Device Name:

- Proprietary Name: IRIS – High Strength Glass Ceramic
- Classification Name: Porcelain powder for clinical use
- CFR Number: 21CFR 872.6660
- Device Class: II
- Product Code: EIH

3. Predicate Device:

IPS e.max CAD (Ivoclar Vivadent, Inc.) - K051705

4. Description of Device:

IRIS - High Strength Glass Ceramic is a system of glass ceramic dental materials based on zirconia reinforced lithium silicate chemistries and feldspathic veneering ceramics and accessories optimized to be compatible with IRIS glass ceramics. The system consists of:

A. IRIS Flex: High Strength Glass Ceramic (HSGC) CAD CAM blanks provided in the fully crystallized state, for machining and subsequent placement.

B. IRIS CAD: High Strength Glass Ceramic (HSGC) CAD CAM blanks provided in the partially crystallized state, for machining, crystallization firing, and subsequent placement.

C. Veneering ceramics provided in powder/paste forms and are intended for optional esthetic characterization of the CAD CAM restorations.

IRIS materials may be veneered with a compatible dental veneering ceramic or can be used as anatomically shaped full-contour restorations without veneering.

5. Indications for Use:

IRIS is a system of precrystallized and/or fully crystallized zirconia reinforced lithium silicate glass ceramics and veneering ceramics processed through CAD-CAM techniques for the fabrication of:

- Single unit dental restorations, for example all-ceramic crowns, inlays, onlays and veneers.

IRIS can be used as a substructure which is then veneered with compatible veneering ceramic or can be used for full-contour application (without veneering) as well.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics.

IRIS is system of glass ceramic materials based on zirconia-reinforced lithium silicate chemistries processed through CAD-CAM techniques and feldspathic veneering ceramics and accessories which are optimized to be compatible with IRIS glass ceramics. The components of the IRIS system and their ISO classifications and usages are outlined below.

Table 5.1: IRIS System Components, ISO classifications and Clinical Usage:

IRIS Component	ISO 6872 Classification	Clinical Usage
A: IRIS Flex: Fully crystallized Blank	Type II, Class 2	Adhesively cemented, aesthetic or substructure ceramic for single-unit anterior or posterior prostheses.
B: IRIS CAD: Partially Crystallized Blank	Type II, Class 3	Aesthetic-ceramic: adhesively or non-adhesively cemented, single-unit, anterior or posterior prostheses
C: IRIS Veneering Ceramic	Type II, Class 1	Aesthetic ceramic for coverage of a metal or a ceramic substructure.

The flexural strength of IRIS Flex materials can be raised to >300 MPa through an optional glaze firing process.

The chemical composition and technological characteristics of the IRIS – High Strength Glass Ceramic are similar to those of the predicate device.

Non-Clinical Performance Data.

Physical Properties

Measurements of the physical characteristics showed that the IRIS – High Strength Glass Ceramic materials have mechanical (flexural strength) and chemical stability (solubility) comparable to the predicate device, and meet ISO 6872 criteria for the designated indications. Simulated life testing (thermal cycling, mechanical loading) verified the long-term stability of the IRIS – High Strength Glass Ceramic in comparison with the predicate device.

Toxicological Testing

Testing according to ISO 10993-1:2009 (*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*) was completed to characterize the biocompatibility of IRIS – High Strength Glass Ceramic materials with respect to cytotoxicity, sensitization, intracutaneous reactivity/irritation, systemic toxicity, and genotoxicity. Results of the testing conducted in accordance support the biocompatibility of the IRIS – High Strength Glass Ceramic.

Clinical Performance Data.

Not applicable. No human clinical testing was conducted to support the substantial equivalence of the IRIS – High Strength Glass Ceramic.

Conclusion Regarding Substantial Equivalence

The IRIS – High Strength Glass Ceramics have the same intended use, similar indications and the same fundamental technological characteristics as the predicate device. Performance testing was conducted with reference to applicable standards as well as in comparison to the predicate device. Toxicological testing verified the biocompatibility of the IRIS – High Strength Glass Ceramic. The results of the design, intended use, and indications for use comparisons as well as the results of the comparative performance testing and biocompatibility testing support the substantial equivalence of the IRIS – High Strength Glass Ceramic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 22, 2013

Ms. Helen Lewis
Director, Corporate Regulatory Affairs
DENTSPLY International, Incorporated
21 West Philadelphia Street, Suite 60W
YORK PA 17405

Re: K123615
Trade/Device Name: IRIS – High Strength Glass Ceramic
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: November 20, 2012
Received: November 29, 2012

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123615

Device Name: IRIS – High Strength Glass Ceramic

Indications for Use:

IRIS – High Strength Glass Ceramic is a system of precrystallized and/or fully crystallized zirconia reinforced lithium silicate glass ceramics and veneering ceramics processed through CAD-CAM techniques for the fabrication of:

- Single unit dental restorations, for example all-ceramic crowns, inlays, onlays and veneers.

IRIS can be used as a substructure which is then veneered with IRIS veneering ceramic or can be used for full-contour application (without veneering) as well.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner
2013.02.14
10:20:01 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123615